REMARKS

This Letter and Response to Final Rejection is respectfully submitted in order to transmit copies of the Request for Continued Examination, Petition for Extension of Time, Petition to Change Inventorship, the accompanying Assignment and Supplemental Declaration and an Information Disclosure Statement, Form PTO-1449 and accompanying references filed on March 25, 2005, as well as a newly-executed RCE and Petition for Extension of Time. A Sixth IDS, Form PTO-1449 and reference is also enclosed.

An Office Action rejecting the Request for Examination (RCE) was rendered on April 6, 2005 as not being accompanied by a submission as required by 37 CFR 1.114. As the attachments indicate, several papers made up the submission under 37 CFR 1.114, however upon inquiry applicants were informed that reference to the Final Rejection was not made on page 1 of the Letter and Amendment filed on March 25, 2005.

Notwithstanding, applicants respectfully submit that they referred to the Final Rejection on page 6 of the Letter and Amendment filed on March 25, 2005 under "Remarks" and that there was a sufficient submission to meet the requirements of 37 CFR 1.114. In addition, applicants filed an Information Disclosure Statement accompanying the RCE, which also would have fulfilled the requirements of 37 CFR 1.114. Applicants respectfully submit that the RCE met the requirements of 37 CFR 1.114 and was timely filed in conjunction with the previous Petition for Extension of Time. Thus, applicants should **not** be charged for any additional time extensions. However, in an abundance of caution, applicants are submitting herewith an additional Petition for Extension of Time and an additional RCE.

Applicants respectfully amend the Specification of the above-captioned patent application in order to correct the claim of benefit of priority to Provisional Patent Application No. 60/069,797 filed December 16, 1997. This claim of priority was inadvertently omitted in the original Declaration and was only discovered upon recent review of the application file. Applicants also respectfully submit herewith a Supplemental Declaration which both reflects the proper inventorship and amends the Declaration to reflect the relationship between the above-identified patent application and Provisional Patent Application No. 60/069,797, filed December 16, 1997, which was

inadvertently omitted from the original declaration. Applicants respectfully request that the claim of the benefit of priority from Provisional Patent Application No. 60/069,797 be granted.

Applicants also respectfully submit that the inventorship of the above-identified patent application inadvertently omitted Dr. Michael Costanzo when the application was originally filed. The remaining inventors are in agreement with adding Dr. Costanzo to the inventorship, as evidenced by the attached Petition to Change Inventorship and Supplemental Declaration.

The Final Rejection of October 25, 2004 rejected claims 24 and 28-35 under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. Claims 24, 28-36, 38, 40, 44-47 and 58 were further rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka and JP 62036304 (Katsumi).

Applicants respectfully request reconsideration of the above-mentioned rejections under 35 U.S.C. 102 and 103(a) in light of the foregoing amendments to the claims and the ensuing discussion.

The Final Rejection rendered October 25, 2004 objects to applicants' distinction between the claimed method set forth in claims 24, 28-36, 28, 40, 44-47 and 58 and Limkatrul et al., Kosaka and Katsumi. As has been noted on several occasions during the course of the prosecution of the above-captioned patent application, soy products containing soy trypsin inhibitor activity were well-known to be dangerous for human ingestion. [See Declaration of Katharine Martin filed March 7, 2002] Soy products containing such activity can cause, for example, gastric distress [Martin Declaration, ¶4], morphological alterations of small intestinal epithelium in calves [Martin Declaration, ¶5] and pancreatic enlargement [Martin Declaration, ¶5].

Thus, whether or not Limkatrul et al., Kosaka or Katsumi indicated that the soybean milk protein administered to the mice in Limkatrul's study contained soy trypsin inhibitory activity, those of ordinary skill in the art would not have expected to be able to administer soybean milk protein containing soy trypsin inhibitory activity to a human being.

Furthermore, Kosaka neither suggests nor describes the claimed method of using soy products. Kosaka merely refers to the use of papain, an enzyme found in papaya, in combination with citric acid, for therapeutic effects on diseases of the circulatory and digestive systems. Kosaka does not teach or suggest topical formulations or applications nor does it

recognize the use of soy products for phagocytosis. The Final Rejection states, with respect to Kosaka, that "...it is known that tofu contains soybeans. Tofu is eaten by humans as a food source. Thus, if tofu can be eaten by a human so can soybean milk." [Final Rejection, p.3] While applicants recognize that tofu is eaten as a food source, tofu is another soy product that is **processed and cooked prior to eating** such that the soy trypsin inhibitory activity is removed from the food. Soybean milk that is intended for human consumption is also processed to remove the dangerous STI activity prior to ingestion. These soy products are distinguishable from the compositions and methods of applicants' invention which **do** contain soy trypsin inhibitory activity. Thus, Kosaka neither suggests nor describes the methods of applicants' invention.

While Katsumi refers to the use of soybean milk as a "cosmetic" or as a preventative for chapped skin or itching, nowhere does it suggest or describe the use of non-denatured soy products containing soy trypsin inhibitory activity for increasing or decreasing phagocytosis.

Applicants therefore respectfully request reconsideration of the rejections of claims 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102 as being anticipated by Limkatrul et al., Kosaka and Katsumi and under 35 U.S.C 103 in view of Limkatrul taken with Kosaka or Katsumi.

The Final Rejection further rejected claims 24, 28-36, 38, 40, 44-47 and 58 provisionally under 35 U.S.C. 102(e) as being anticipated by copending patent application Serial No. 09/110,409 and under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application Serial No. 9/110/409. Should claims become granted in the copending patent application, applicants will address the foregoing provisional rejections.

Applicants respectfully request correction of the claim of the benefit of priority with respect to the abovementioned provisional patent application, addition of Michael Costanzo to the inventorship of the above-captioned patent application and

reconsideration of the rejections set forth in the Final Rejection of October 25, 2004. An early allowance is earnestly solicited.

Respectfully submitted,

By: /Andrea L. Colby/
Andrea L. Colby
(Attorney for Applicants and Assistant Secretary,
Johnson & Johnson
Consumer Companies, Inc.)
Reg. No. 30,194

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 Dated: April 22, 2005

PATENT AND TRADEMARK OFFICE UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. 5255 JBP438 MIRI SEIBERG 09/206,249 **EXAMINER** 04/06/2005 7590 MELLER, MICHAEL V PHILIP S. JOHNSON, ESQ. JOHNSON & JOHNSON PAPER NUMBER ART UNIT ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 1654 DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding

RECEIVED

APR 1 1 2005

J&J PAT. DKT. SECTION



Commissioner for Patents United States Patent and Trademark Office

Washington, D.C. 20231

www.uspto.gov

APPLICATION NUMBER

FORM PTO-2051 (Rev. 3/2001)

FILING DATE

FIRST NAMED APPLICANT

ATTY, DOCKET NO./TITLE

DATE MAILED:

	SALE MALLED:
	NOTICE OF IMPROPER REQUEST FOR CONTINUED EXAMINATION (RCE)
The impr	request for continued examination (RCE) under 37 CFR 1.114 filed on $03.28.05$ is oper for reason(s) indicated below:
	. Continued examination under 37 CFR 1.114 does not apply to an application for a design patent. Applicant may wish to consider filing a continuing application under 37 CFR 1.53(b) or a CPA under 37 CFR 1.53(d).
_ 2	Continued examination under 37 CFR 1.114 does not apply to an application that was filed before June 8, 1995. Applicant may wish to consider filing a continuing application under 37 CFR 1.53(b) or a CPA under 37 CFR 1.53(d).
□ ₃	Continued examination under 37 CFR 1.114 does not apply to an application unless prosecution in the application is closed. If the RCE was accompanied by a reply to a non-final Office action, the reply will be entered and considered under 37 CFR 1.111. If the RCE was <u>not</u> accompanied by a reply, the time period set forth in the last Office action continues to run from the mailing date of that action.
□ 4.	The request was not filed before payment of the issue fee, and no petition under 37 CFR 1.313 was granted. If this application has not yet issued as a patent, applicant may wish to consider filing either under 37 CFR 1.313 to withdraw this application from issue, or a continuing application under 37 CFR 1.53(b).
□ _{5.}	The request was not filed before abandonment of the application. The application was abandoned, or proceedings terminated on Applicant may wish to consider filing a petition under 37 CFR 1.137 to revive this abandoned application.
6.✓	The request was not accompanied by the fee set forth in 37 CFR 1.17(e) as required by 37 CFR 1.114. Since the application is not under appeal, the time period set forth in the final Office action or notice of allowance continues to run from the mailing date of that action or notice.
A)7.	The request was not accompanied by a submission as required by 37 CFR 1.114. Since the application is not under appeal, the time period set forth in the final Office action or notice of allowance continues to run from the mailing date of that action or notice.
reques	If a request for a continued prosecution application (CPA) under 37 CFR 1.53(d) has been filed in ity or plant application (including a previously filed CPA) that was filed on or after May 29, 2000, the st for a CPA has been treated as a RCE because the CPA practice no longer applies to such ation. The constructive RCE, however, is improper for reason(s) indicated above.
^	A copy of this notice MUST be returned with any reply.
	ne reply and any questions about this notice to:
100	1000 571-272-0522
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Serial No. 09/206-249	Docket No. <u>Uβρ. 438</u> By. <u>ALC</u>
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Entitled: Compositions and Method	18 for Regulating Phagocytosis S PATENT OFFICE ON THE DATE STAMPED HEREON:
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☐ Fee Transmittal	☐ Specification pgs
Charge to Deposit Account 10-0750	Claims
Priority Document	☐ Drawings sheets
	☐ Preliminary Amendment
MIDS-Form 1449 W Refs. 9 Fifth Supp.	DEMENTAL Sequence Listings/Diskette
Extension of Time	■ Biological Deposit Declaration
□ PTO 1390 (PCT)	DI Other Transmittal Letter 4
	' Amendment

PTO/SB/30 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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REQUEST				
FOR				
CONTINUED EXAMINATION				

(RCE)

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

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Application Number	09/206,249
Filing Date	December 7, 1998
First Named Inventor	Seiberg et al.
Group Art Unit	1654
Examiner Name	M. Meller
Attorney Docket Number	JBP-438

	This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may					
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established RCE pro	actice.					
1. Submission requir	ed under 37 C.F.R. § 1.114					
a. Previous	ly submitted	D. C. 4.446 proviously filed on				
i, 🔲 Cor	sider the amendment(s)/reply under 37 C.F. (any unentered amendment(s) referred to	H. § 1.116 previously liled on				
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iii. 🔲 Oth	er					
b. 🛛 Enclosed	d ·					
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	ormation Disclosure Statement (IDS) her Form 1449 with copies of references					
l iv. ⊠ Oth v. ⊠ Pet	ition To Correct Inventorship		·			
	into the control of t		ļ.			
2. Miscellaneous	sion of action on the above-identified applica	tion is requested under 37 C.F.R. &	1.103(c) for a period of			
a. Suspense months. (Period of sus	spension shall not exceed 3 months; Fee unc	ler 37 C.F.R. § 1.17(i) required.)	, , , , , , , , , , , , , , , , , , ,			
b. Other	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	•	1			
3. Fees - The RCE fe	ee under 37 C.F.R. § 1.17(e) is required by 3	7 C.F.R. § 1.114 when the RCE is	filed			
a. The Dire	ector is hereby authorized to charge the follow	wing fees, or credit any overpayme	ents,			
to Depo	sit Account No. 10-0750/JPB438/ALC.					
i 🖂 RC	i. IXI RCE fee is required under 37 C.F.R. § 1.17(e)					
ii. Extension of Time (37 C.F.R. §§ 1.136 and 1.17)						
iii. Other						
b. Check in the amount of \$enclosed						
c. Payment by credit card (Form PTO-2038 enclosed)						
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED						
Name (print/type)	Andrea L. Colby	Registration No.	30,194			
Signature	/Andrea L. Colby/	Date	March 25, 2005			
·	CERTIFICATE OF MAIL	ING OR TRANSMISSION				
I hereby certify that thi	s correspondence is being deposited with the	United States Postal Service with	sufficient postage as first class			
mail in an envelope addressed to: Commissioner For Patents, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and						
Trademark Office on:						
Name (print/type)	Andrea L. Colby – Reg. No. 30,194	I Data	Moreh 05, 2005			
Signature	/Andrea L. Colby/	Date	March 25, 2005			

PTO/SB/30 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required

REQUEST
FOR
CONTINUED EXAMINATION
(RCE)
TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

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Application Number	09/206,249		
Filing Date	December 7, 1998		
First Named Inventor	Seiberg et al.		
Group Art Unit	1654		
Examiner Name	M. Meller		
Attorney Docket Number	JBP-438		

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filling a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Final Rule, 65 Fed. Reg. 50092 (Aug. 16, 2000); Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.					
1. Submission required under 37 C.F.R. § 1.114					
a. Previously submitted					
i. Consider the amendment(s)/reply under 37 C.F.I					
(any unentered amendment(s) referred to					
ii. Consider the arguments in the Appeal Brief or Re	eply Brief previously filed of				
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b. Enclosed					
i. 🔀 Amendment/Reply		·			
ii 🔯 Affidavit(s)/Declaration(s)		·			
iii 🖂 Information Disclosure Statement (IDS)	•	1			
iv. Other Form 1449 with copies of references					
v. Petition To Correct Inventorship					
2. Miscellaneous					
a. Suspension of action on the above-identified applicat	ion is requested under 37 C.F.R. §	1.103(c) for a period of			
months. (Period of suspension shall not exceed 3 months; Fee und	er 37 C.F.R. § 1.17(i) required.)				
b. Other	•	•			
3. Fees - The RCE fee under 37 C.F.R. § 1.17(e) is required by 37	7 C.F.R. § 1.114 when the RCE is	filed			
a The Director is hereby authorized to charge the follow	ving fees, or credit any overpayme	nts,			
to Deposit Account No. 10-0750/JPB438/ALC.					
i. RCE fee is required under 37 C.F.R. § 1.17(e)					
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SIGNATURE OF APPLICANT, AT					
Name (print/type) Andrea L. Colby	Registration No. Date	30,194 March 25, 2005			
Signature /Andrea L. Colby/		March 25, 2005			
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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class					
mail in an envelope addressed to: Commissioner For Patents, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and					
Trademark Office on: Name (print/type) Andrea L. Colby – Reg. No. 30,194					
Traine (print type)					
Signature /Andrea L. Colby/	Date	Watch 20, 2000			

PTO/SB/30 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

Andrea L. Colby - Reg. No. 30,194

/Andrea L. Colby/

Name (print/type)

Signature

to respond to a collection of information unles	is it displays a valid OMB control number.
Application Number	09/206,249
Filing Date	December 7, 1998
First Named Inventor	Seiberg et al.
Group Art Unit	1654
Examiner Name	M. Meller
Attorney Docket Number	JBP-438

March 25, 2005

NOTE: 37 C.F.R. § 1.114 wish to consider filing a con	tinued Examination (RCE) under 14 is effective on May 29, 2000. If the above-iden ontinued prosecution application (CPA) under 37 at provisions of the AIPA. See Changes to Applicate, 2000); interim Rule, 65 Fed. Reg. 14865 (Mar. 2	ified application was tiled pnor to May 29, 20 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a R tion Examination and Provisional Application	OU, applicant may CE to be eligible for Practice, Final Rule, 65			
1. Submission required ur	nder 37 C.F.R. § 1.114					
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	any unentered amendment(s) refer		an .			
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iii. 🗍 Other	•					
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	tion Disclosure Statement (IDS)		ļ			
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a. Suspension of	of action on the above-identified ap	o under 37 C F.R. & 1.17(i) red	uirod)			
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1	is hereby authorized to charge the	following fees or credit any or	vernayments			
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i Deposit Acc	to Deposit Account No. 10-0750/JPB438/ALC. i. RCE fee is required under 37 C.F.R. § 1.17(e)					
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iii. 🗍 Other		•				
b. Check in the a	amount of \$ enclosed					
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	NATURE OF APPLICANT					
1141110 (5111101) 507	rea L. Colby	Registration No.	30,194			
Signature /Andr	irea L. Colby/	Date	March 25, 2005			
		MAILING OR TRANSMISSION				
I hereby certify that this corre mail in an envelope addresse	espondence is being deposited wi ed to: Commissioner For Patents	th the United States Postal Se , Washington, DC 20231, or fa	ervice with sufficient postage as first class acsimile transmitted to the U.S. Patent and			

Date

Applicants:

Miri Seiberg, et al.

Serial No.:

09/206,249

Art Unit: 1651

Filed

July 6, 1998

Examiner:

M. Meller

For

METHOD FOR REGULATING PHAGOCYTOSIS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2005
(Date of Deposit)
Andrea L. Colby - Reg. No. 30,194
(Name of applicant, assignee, or Registered Representative)
/Andrea L. Colby/
(Signature)
March 25, 2005
(Date of Signature)

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER AND AMENDMENT

Dear Sir:

This Letter respectfully transmits the attached Request for Continued Prosecution, Petition for Extension of Time, Petition to Change Inventorship, the accompanying Assignment and Supplemental Declaration and an Information Disclosure Statement, Form PTO-1449 and accompanying references.

Amendments to the Specification being on page 2 of this paper.

Listing of the Claims begin on page 3 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Specification:

Please insert the following paragraph at page 1, line 1 of the Specification:

This application is a nonprovisional patent application based upon provisional patent application U.S. Serial No. 60/069,797, filed December 16, 1997.

Listing of Claims:

- 1-22. (cancelled)
- 23. (cancelled)
- 24. (previously presented) A method of decreasing phagocytosis or ICAM-1 expression in a mammalian cell in need thereof, comprising contacting the cell with a therapeutically phagocytosis- or ICAM-1 decreasing effective amount of soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
- 25. (cancelled)
- 26-27. (cancelled)
- 28. (original) The method of claim 24, wherein the agent inhibits the PAR-2 pathway.
- 29. (original) The method of claim 24, wherein the agent is selected from the group consisting of a soybean derivative and a serine protease inhibitor.
- 30. (previously presented) The method of claim 29, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.
- 31. (original) The method of claim 23 or 24, wherein the mammalian cell is a PAR-2-expressing cell.
- 32. (original) The method of claim 31, wherein the mammalian cell is selected from the group consisting of a keratinocyte, a fibroblast, and a professional phagocyte.
- 33. (original) The method of claim 32, wherein the mammalian cell is a keratinocyte.
- 34. (original) The method of claim 32, wherein the mammalian cell is a fibroblast.
- 35. (original) The method of claim 32, wherein the mammalian cell is a professional phagocyte.

- 36. (original) The method of claim 23 or 24, wherein the mammalian cell is a human cell.
- 37. (cancelled)
- 38. (previously presented) A method of treating a mammal afflicted with a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administered to the cells in need thereof a phagocytosis- or ICAM-1-decreasing therapeutically effective amount of soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
- 39. (cancelled)
- 40. (previously presented) A method of preventing a mammal afflicted with a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administering to the cells in need thereof a prophylatically phagocytosis- or ICAM-1 decreasing effective amount of soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
- 41. (cancelled)
- 42. (cancelled)
- 43. (cancelled)
- 44. (original) The method of claim 38 or 40, wherein the agent inhibits the PAR-2 pathway.
- 45. (previously presented) The method of claim 38 or 40, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.

- 46. (previously presented) The method of claim 45, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.
- 47. (original) The method of claim 37, 38, 39 or 40, wherein the appropriate cells are PAR-2-expressing cells.
- 48. (cancelled)
- 49. (cancelled)
- 50. (cancelled)
- 51. (cancelled)
- 52. (cancelled)
- 53. (cancelled)
- 54. (cancelled)
- 55. (cancelled)
- 56. (cancelled)
- 57. (cancelled)
- 58. (original) The method of claim 37, 38, 39 or 40, wherein the mammal is a human.
- 59-74. (cancelled)

REMARKS

This Letter and Response to Final Rejection is respectfully submitted in order to transmit the attached Request for Continued Prosecution, Petition for Extension of Time, Petition to Change Inventorship, the accompanying Assignment and Supplemental Declaration and an Information Disclosure Statement, Form PTO-1449 and accompanying references.

Applicants respectfully amend the Specification of the above-captioned patent application in order to correct the claim of benefit of priority to Provisional Patent Application No. 60/069,797 filed December 16, 1997. This claim of priority was inadvertently omitted in the original Declaration and was only discovered upon recent review of the application file. Applicants also respectfully submit herewith a Supplemental Declaration which both reflects the proper inventorship and amends the Declaration to reflect the relationship between the above-identified patent application and Provisional Patent Application No. 60/069,797, filed December 16, 1997, which was inadvertently omitted from the original declaration. Applicants respectfully request that the claim of the benefit of priority from Provisional Patent Application No. 60/069,797 be granted.

Applicants also respectfully submit that the inventorship of the above-identified patent application inadvertently omitted Dr. Michael Costanzo when the application was originally filed. The remaining inventors are in agreement with adding Dr. Costanzo to the inventorship, as evidenced by the attached Petition to Change Inventorship and Supplemental Declaration.

The Final Rejection of October 25, 2004 rejected claims 24 and 28-35 under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. Claims 24, 28-36, 38, 40, 44-47 and 58 were further rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka and JP 62036304 (Katsumi).

Applicants respectfully request reconsideration of the above-mentioned rejections under 35 U.S.C. 102 and 103(a) in light of the foregoing amendments to the claims and the ensuing discussion.

The Final Rejection rendered October 25, 2004 objects to applicants' distinction between the claimed method set forth in claims 24, 28-36, 28, 40, 44-47 and 58 and Limkatrul

et al., Kosaka and Katsumi. As has been noted on several occasions during the course of the prosecution of the above-captioned patent application, soy products containing soy trypsin inhibitor activity were well-known to be dangerous for human ingestion. [See Declaration of Katharine Martin filed March 7, 2002] Soy products containing such activity can cause, for example, gastric distress [Martin Declaration, ¶4], morphological alterations of small intestinal epithelium in calves [Martin Declaration, ¶5] and pancreatic enlargement [Martin Declaration, ¶5].

Thus, whether or not Limkatrul et al., Kosaka or Katsumi indicated that the soybean milk protein administered to the mice in Limkatrul's study contained soy trypsin inhibitory activity, those of ordinary skill in the art would not have expected to be able to administer soybean milk protein containing soy trypsin inhibitory activity to a human being.

Furthermore, Kosaka neither suggests nor describes the claimed method of using soy products. Kosaka merely refers to the use of papain, an enzyme found in papaya, in combination with citric acid, for therapeutic effects on diseases of the circulatory and digestive systems. Kosaka does not teach or suggest topical formulations or applications nor does it recognize the use of soy products for phagocytosis. The Final Rejection states, with respect to Kosaka, that "...it is known that tofu contains soybeans. Tofu is eaten by humans as a food source. Thus, if tofu can be eaten by a human so can soybean milk." [Final Rejection, p.3] While applicants recognize that tofu is eaten as a food source, tofu is another soy product that is processed and cooked prior to eating such that the soy trypsin inhibitory activity is removed from the food. Soybean milk that is intended for human consumption is also processed to remove the dangerous STI activity prior to ingestion. These soy products are distinguishable from the compositions and methods of applicants' invention which do contain soy trypsin inhibitory activity. Thus, Kosaka neither suggests nor describes the methods of applicants' invention.

While Katsumi refers to the use of soybean milk as a "cosmetic" or as a preventative for chapped skin or itching, nowhere does it suggest or describe the use of non-denatured soy products containing soy trypsin inhibitory activity for increasing or decreasing phagocytosis.

Applicants therefore respectfully request reconsideration of the rejections of claims 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102 as being anticipated by Limkatrul et al., Kosaka and Katsumi and under 35 U.S.C 103 in view of Limkatrul taken with Kosaka or Katsumi.

The Final Rejection further rejected claims 24, 28-36, 38, 40, 44-47 and 58 provisionally under 35 U.S.C. 102(e) as being anticipated by copending patent application Serial No. 09/110,409 and under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application Serial No. 9/110/409. Should claims become granted in the copending patent application, applicants will address the foregoing provisional rejections.

Applicants respectfully request correction of the claim of the benefit of priority with respect to the abovementioned provisional patent application, addition of Michael Costanzo to the inventorship of the above-captioned patent application and reconsideration of the rejections set forth in the Final Rejection of October 25, 2004. An early allowance is earnestly solicited.

Respectfully submitted,

By: /Andrea L. Colby/
Andrea L. Colby
(Attorney for Applicants and Assistant Secretary,
Johnson & Johnson
Consumer Companies, Inc.)
Reg. No. 30,194

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 Dated: March 25, 2005

Applicants:

Seiberg, et al

Serial No.:

09/206,249

Art Unit: 1651

Filed

December 7, 1998

Examiner: Meller

For

METHOD FOR REGULATING PHAGOCYTOSIS

I hereby certify that this correspondence is being faxed to: Commissioner for Patents, Washington, DC 20231 on

> March 25, 2005 (Date of Deposit)

Andrea L. Colby - Reg. No. 30,194 (Name of applicant, assignee, or Registered Representative

/Andrea L. Colby/
(Signature)

March 25, 2005

(Date of Signature)

Commissioner For Patents Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME AND AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicants petition the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated October 25, 2004 for two(2) months from January 25, 2005 to March 25, 2005. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-0750/JBP0438/ALC in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby Reg. No. 30,194 Attorney for Applicant(s)

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 DATE: March 25, 2005

Applicants:

Seiberg, et al

Serial No.:

09/206,249

Art Unit: 1651

Filed

December 7, 1998

Examiner: Meller

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METHOD FOR REGULATING PHAGOCYTOSIS

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> March 25, 2005 (Date of Deposit)

Andrea L. Colby - Reg. No. 30,194 (Name of applicant, assignee, or Registered Representative

/Andrea L. Colby/
(Signature)

March 25, 2005
(Date of Signature)

Commissioner For Patents Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME AND AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicants petition the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated October 25, 2004 for two(2) months from January 25, 2005 to March 25, 2005. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-0750/JBP0438/ALC in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby Reg. No. 30,194 Attorney for Applicant(s)

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 DATE: March 25, 2005

Applicants:

Seiberg, et al

Serial No.:

09/206,249

Art Unit: 1651

Filed

December 7, 1998

Examiner: Meller

For

METHOD FOR REGULATING PHAGOCYTOSIS

I hereby certify that this correspondence is being faxed to: Commissioner for Patents, Washington, DC 20231 on

March 25, 2005
(Date of Deposit)

Andrea L. Colby - Reg. No. 30,194 (Name of applicant, assignee, or Registered Representative

/Andrea L. Colby/
(Signature)

March 25, 2005
(Date of Signature)

Commissioner For Patents Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME AND AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicants petition the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated October 25, 2004 for two(2) months from January 25, 2005 to March 25, 2005. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-0750/JBP0438/ALC in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby Reg. No. 30,194 Attorney for Applicant(s)

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 DATE: March 25, 2005

Applicants: Miri Seiberg, et al.

Serial No.: 09/206,249 Art Unit: 1651

Filed: July 6, 1998 Examiner: M. Meller

For : METHOD FOR REGULATING PHAGOCYTOSIS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2005 (Date of Deposit)

Andrea L. Colby - Reg. No. 30,194 (Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/
(Signature)

March 25, 2005
(Date of Signature)

Assistant Commissioner for Patents Washington, D.C. 20231

PETITION, AMENDMENT, STATEMENT OF ASSIGNEE AND FEE TO CORRECT INVENTORSHIP UNDER 37 CFR §1.48(a)

Dear Sir:

Applicants hereby petition to correct the inventorship in the above-identified patent application.

Please add the following inventor: Michael J. Costanzo in the above-identified patent application.

The following documents are attached hereto:

- (1) a Statement of Facts verified by the originally named inventors establishing when the error without deceptive intention was discovered and how it occurred; and
 - (2) a Declaration by each actual inventor.

Johnson & Johnson Consumer Companies, Inc., Grandview Road, Skillman, NJ 08558 hereby consents to the correction of inventorship filed herewith.

The Assignment for the above-identified patent application was submitted to the Patent and Trademark Office on May 3, 1999 (Reel No. 9933710) to Johnson & Johnson Consumer Companies, Inc., a copy of which is attached hereto.

Please charge the fee set forth in 37 CFR §1.17(h) to Deposit Account No.: 10-0750/JBP438/ALC. A triplicate copy of this sheet is attached hereto.

Respectfully submitted,

By: /Andrea L. Colby/
Andrea L. Colby
(Attorney for Applicants and Assistant Secretary,
Johnson & Johnson
Consumer Companies, Inc.)
Reg. No. 30,194

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 Dated: March 25, 2005

Applicants: Miri Seiberg et al. Confirmation No.: 5255

Serial No.: 09/206,249 Art Unit: 1654

Filed : December 7, 1998 Examiner: Michael V. Meller

For : Compositions and Methods for Regulating

Phagocytosis and ICAM-1 Expression

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2005
(Date of Deposit)

Andrea L. Colby, Reg. No. 30,194
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/
(Signature)

March 25, 2005

(Date of Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statement mailed on September 1, 2004.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

In ac	cordance	e with	§1.12	9(a)	, t.	his Into	rmation	
Disclosure Stat	ement is	being	file	d in	CO	nnection	with [] the
first or [seco	nd After	Final	Subm	issi	on,	therefo	re:	
	Statemen	nt in A	ccord	lance	wi	th §1.97	'(e)	
	(attache	ed); or						
	Please	charge	Depos	it A	ccc	ount No.	10-	
	0750/	/	the	fee	of	\$180.00	as set	forth
	in §1.1	7(p).				•		

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

	Statement in Accordance with \$1.97(e)
	(attached); or
	Please charge Deposit Account No. 10-
	0750/ / the fee of \$180.00 as set forth
	in §1.17(p).
In ac	ccordance with §1.97(d), this Information
Disclosure Stat	ement is being filed after the mailing date of
either a Final	Action under §1.113 or a Notice of Allowance
under §1.311 h	out before the payment of the Issue Fee.
Applicant(s) he	ereby petition(s) for consideration of this
	sclosure Statement. Included are: Statement in
Accordance with	1 §1.97(e) as set forth below and the fee of
·	forth in §1.17(p).
	es of each of the references listed on the
attached Form I	PTO-1449 are enclosed herewith.
□ Coni	es of only foreign patent documents and non-
	are are enclosed in accordance with 37 CFR 1.98
	J.S. patents and each U.S. patent application
-	sted on the attached Form PTO-1449 are not
	se this U.S. patent application was filed after
	or this international application has entered the
	under 35 USC §371 after June 30, 2003 (see USPTO
waiver of requi	rement under 37 CFR 1.98 (a)(2)(i).
	e are no listed references which are not in the
English languag	je.
	relevance of those listed references which are
not in the Engl	lish language is as follows: .

Attached are copies of search report(s) from
corresponding patent application(s), which are listed on the
attached Submission Under MPEP 609 D.
—
Attached are the following non-published pending
patent applications which may be deemed relevant, which are
listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/JBP0438/ALC. This form is submitted in triplicate.

Respectfully submitted,

/Andrea L. Colby/ Andrea L. Colby Reg. No. 30,194 Attorney for Applicants

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2793 DATED: March 25, 2005 Under the Paperwork Reduction Act of 1995, no persons are required

Substitute	for form	1449A	VPTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 1 of 1

to respond to a domestion of information drife	ss it displays a valid Civid Control Hulliper.
Confirmation Number	5255
Application Number	09/206,249
Filing Date	12/07/1998
First Named Inventor	Miri Seiberg
Group Art Unit	1654
Examiner Name	Michael V. Meller
Attorney Docket Number	JBP438

U.S. PATENT DOCUMENTS U.S. Patent Document Date of Publication Pages, Columns, Lines, Name of Patentee or Applicant Kind Code⁴ Exam Cite of Cited Document where relevant passages or of Cited Document Initials (if known) relevant figures appear Number mm-dd-yyyy No.1 Α Kligman 07-29-1986 4,603,146 4,727,088 Α Scott et al. 02-23-1988 09-23-1997 5.670,547 Α Milstein et al.

FOREIGN PATENT DOCUMENTS Foreign Patent Document Date of Pages, Columns, Publication of Lines, where relevant Name of Patentee or Cited Document passages or relevant Fxam Cite Applicant of Cited Document mm-dd-yyyy figures appear Number⁴ KindCode⁵ Initials Office³ ATHER DRICK ART - NON DATENT LITERATURE DOCUMENTS

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published linitials No.1				

Examiner	Date	
Signature	Considered	
Signature		

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Applicants: Miri Seiberg, et al.

Serial No.: 09/206,249 Art Unit: 1651

Filed: December 7, 1998 Examiner: M. Meller

For : METHOD FOR REGULATING PHAGOCYTOSIS

Assistant Commissioner for Patents Washington, D.C. 20231

STATEMENT OF FACTS UNDER 37 CFR §1.48(a)

Dear Sir:

We, Miri Seiberg, Stanley S. Shapiro, and Magdalena Eisinger, the originally-named inventors to the above-mentioned application, declare and say:

During the preparation of the above-identified patent application, Michael J. Costanzo provided Andrea Colby, the attorney for Applicants, with some facts that suggested that he should be included as an inventor to the above-referenced application.

At the time that this application was filed, the Applicants inadvertently and without deceptive intent failed to include Mr. Costanzo as an inventor.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

Date: 1/6/05 2004

Date: 117/05 2004

Date: 1/6/05 2004

Miri Seiberg

Stanley S. Shapiro

Magdalena Eisinger

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECL	DECLARATION			et Number	JBP438	.	Ì
	AND POWER OF ATTORNEY		First Named In	ventor	Miri Sei	hera	
	TY OR DESIGN		COMPLETE IF KNOWN				
• • • • • • •	APPLICATION CFR 1.63)		Application Nu		09/206		
Declaration Submitted with Initial Filing	OR Initial Filing (Sure	charge	Filing Date		Decem	ber 7, 1998	
	(37 CFR 1.16(e))	required)	Group Art Unit		1654		
	·		Examiner Nan	ne	Michae	el V. Meller	
As a below named inventor	, I hereby declare that:	•					
My residence, mailing address, and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:							
METHODS FOR REGULATING PHAGOCYTOSIS (Title of the Invention)							
the specification of which							
is attached hereto							
OR							
was filed on (MM/DD/YY Number 09/206,249 and was a			Application Nur	nber or PCT	Internati	ional Applicati	ion
I hereby state that I have revi amended by any amendment	iewed and understand the specifically referred to	he contents above.	s of the above id	entified spe	cification	, including the	e claims, as
I acknowledge the duty to dis continuation-in-part application and the national or PCT inter	ons, material information national filing date of the	n which bed e continuat	came available t ion-in-part appli	etween the cation.	filing dat	e of the prior	application
I hereby claim foreign priority inventor's certificate, or 365(a United States of America, list or inventor's certificate, or an priority is claimed.	 a) of any PCT internation ted below and have also 	nal applica didentified dication ha	tion which desig below, by check ving a filing date	inated at leaking the box before that	ast one co , any fore t of the a	ountry other the sign application on the sign application on the sign and the sign application on the sign application of the	nan the on for patent which
Prior Foreign Application Number(s)	Country		Filing Date DD/YYYY)	Priori Not Clai		Certifie Attac YES	

the same and the same are listed or	a supplemental priority data sheet PTO/SB/02B attached hereto:
I I DARRITONALINE COLO II ADDIICALIOII IIUIIDEIS ALE IISLEU OI	Ta supplemental phonty data sheet F TO/SD/02B attached hereto.

- .

DECLA	RATION - Utility or Design Patent Appl	ication
I hereby claim the benefit under 35 U.S.	C. 119(e) of any United States provisional app	plication(s) listed below.
Application Number(s) 60/069797	Filing Date (MM/DD/YYYY) 12/16/1997	Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
as the subject matter of each of the claims provided by the first paragraph of Title 35, defined in Title 37, Code of Federal Regul pational or PCT international filing date of	Inited States Code, §120 of any United States of this application is not disclosed in the prior United States Code, §112, I acknowledge the ations, §1.56(a) which occurred between the fithis application:	United States application in the manner duty to disclose material information as disclose the prior application and the
Application Serial No.	Filing Date	Status
		Patented Patented Patented
I hereby appoint:		
Practitioners at Customer NumberAND	000027777 -	Place Customer Number Bar Code Label Here
Practitioner(s) named below: Name .	Registration Number	
States Patent and Trademark Office con	secute the application identified above, and to nected therewith. ne number (732) 524-	to transact all business in the United
	omer Number r Co de Label 000027777 OR	☐ Correspondence address below
Name:		
Address:		
Address:		
City:	State:	ZIP
Country	Telephone:	Fax:

I hereby declare that all statements made herein information and belief are believed to be true; are that willful false statements and the like so made U.S.C. 1001 and that such willful false statemen issued thereon.	nd further that the e are punishable l	se state	ments were ma r imprisonmen	ade with the knowledge t, or both, under 18	
NAME OF SOLE OR FIRST INVENTOR:	A petition has	been filed	for this unsigned	inventor	
Given Name (first and middle [if any]) Miri	Family I or Surn		Seiberg		
Inventor's > 3'5 ' >'//	<u> </u>		Date/	16/05	
Residence: City Princeton Stat	te NJ	Country	USA	Citizenship US and Israel	
Mailing Address 168 Herrontown Road					
	te NJ	ZIP 085		Country USA	
I hereby declare that all statements made herein information and belief are believed to be true; at that willful false statements and the like so made U.S.C. 1001 and that such willful false statement issued thereon.	nd further that the e are punishable	ese state by fine o	ements were m or imprisonme:	nade with the knowledge	
NAME OF SECOND INVENTOR:	A petition has	been file	d for this unsigne	d inventor	
Given Name (first and middle [if any]) Stanley S.	Family or Surr		Shapiro	·	
Inventor's Signature			Date 1	20/05	
Residence: City State	te NJ	Countr	y USA	Citizenship USA	
Mailing Address		T	-		
Q1Ly	te NJ	ZIP		Country USA	
I hereby declare that all statements made herein information and belief are believed to be true; a that willful false statements and the like so mad U.S.C. 1001 and that such willful false statements sued thereon.	nd further that the are punishable	ese stat by fine	ements were r or imprisonme	made with the knowledge ent, or both, under 18	
NAME OF THIRD INVENTOR:	☐ A petition has	s been file	ed for this unsigne	ed inventor	
Given Name (first and middle [if any]) Magdalena G.	Family or Sur		Eisinger		
Inventor's Signature			Date // 6	/05	
Residence: City Demarest Sta	te NJ	Count	ry USA	CitizenshipUSA	
Mailing Address 30 Pine Terrace		T	-		
City Demarest Sta I hereby declare that all statements made herei	te NJ	ZIP 0		Country USA	
information and belief are believed to be true; a that willful false statements and the like so mad U.S.C. 1001 and that such willful false statements are the statements.	ind further that th le are punishable	ese sta	tements were or imprisonm	made with the knowledge ent, or both, under 18	
NAME OF FOURTH INVENTOR:	tition has been filed	for this u	nsigned inventor		

iven Name rst and middle [if any]) Michael J.	Family Name or Surname	Costanzo	
nventor's ignature	Date:		
tesidence: Citylvyland	State PA	Country USA	CitizenshipUSA
ailing Address 14 Breckenridge Drive			
ty Ivyland	State PA	ZIP 18974	Country USA

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLA	ARATION		Attorney Docke	t Number	JBP438		
	AND F ATTORNEY		First Named In	ventor	Miri Seil	berg	
FOR UTILIT	FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)			COMPLE	TE IF KNO	OWN	
			Application Nu		09/206,	, ,	
Declaration Submitted with Initial Filing			Filing Date		Decemb	ber 7, 1998	
	(37 CFR 1.16(e))	required)	Group Art Unit		1654		
			Examiner Nan	ne	Michae	l V. Meller	
As a below named inventor,	I hereby declare that:	;					
My residence, mailing address I believe I am the original, first plural names are listed below) entitled:	and sole inventor (if or of the subject matter w	nly one nan which is clai	ne is listed below med and for whi	n) or an origi ch a patent	nal, first a	and joint inve on the inven	ntor (if tion
	METHODS FOR	R REGULA Title of the	•	YTOSIS		w	
the specification of which		•					
is attached hereto							
OR							
was filed on (MM/DD/YYY Number 09/206,249 and was an			Application Nur	nber or PCT	Internation	onal Applicat	ion
I hereby state that I have revie amended by any amendment	ewed and understand the specifically referred to	he contents above.	s of the above id	entified spe	cification,	including the	e claims, as
I acknowledge the duty to disc continuation-in-part application and the national or PCT intern	ns. material informatior	n which bed	came available t	etween the	n 37 CFR filing date	R 1.56, include e of the prior	ing for application
I hereby claim foreign priority I inventor's certificate, or 365(a) United States of America, liste or inventor's certificate, or any priority is claimed.) of any PCT internation ed below and have also	nal applica didentified dication ha	tion which desig below, by check ving a filing date	nated at leading the box before that	st one co , any forei of the ap	ountry other t ign application oplication on	han the on for paten which
Prior Foreign Application Number(s)	Country		Filing Date DD/YYYY)	Priori Not Clai		Certifie Attac YES	
	ation numbers are liste						

pereby claim the benefit under 35 U.S.C	2. 119(e) of any United States provisional a	pplication(s) listed below.
Application Number(s) 60/069797	Filing Date (MM/DD/YYYY) 12/16/1997	Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
s the subject matter of each of the dalms	Inited States Code, § 120 of any United State of this application is not disclosed in the pric United States Code, § 112, I acknowledge thations, § 1.56(a) which occurred between the this application: Filing Date	he duty to disclose material information as
		Patented Patented
hereby appoint: Practitioners at Customer Number AND	000027777 →	Place Customer Number Bar Code Label Here
Practitioner(s) named below: Name	Registration Number	
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NAME OF SOLE OR FIRST INVENTOR:	☐ A pet	tition has been	iled for this unsig	ned inventor
Given Name (first and middle [if any]) Min		Family Name or Surname	Seiberg	
Inventor's Signature			Date	
Residence: City Princeton	State NJ	Cou	ntry USA	Citizenship US and Israel
Mailing Address 168 Herrontown Road				
City Princeton I hereby declare that all statements made to be a statement of the control of the	State NJ	ZIP	08540	Country USA
I hereby declare that all statements that information and belief are believed to be that willful false statements and the like U.S.C. 1001 and that such willful false s issued thereon.	statements may je	opardize the	validity of the	application or any patent
NAME OF SECOND INVENTOR:	□ Аре	etition has beer	filed for this uns	ignea inventor
Given Name (first and middle [if any]) Stanley S.		Family Name or Surname	Shapiro	
Inventor's Signature			Date	
Residence: City	State NJ	Co	untry USA	CitizenshipUSA
Mailing Address				
	State NJ	ZIF	• •	Country USA
City I hereby declare that all statements ma information and belief are believed to b that willful false statements and the like U.S.C. 1001 and that such willful false issued thereon. NAME OF THIRD INVENTOR:	e true; and furthe e so made are pur statements may jo	nishable by feopardize th	ina or impriso	nment, or both, under 18 ne application or any patent
Given Name (first and middle [if any]) Magdalena G.		Family Nan		
Inventor's Signature			Date	
Residence: City Demarest	State NJ	Co	ountry USA	CitizenshipUSA
Mailing Address 30 Pine Terrace				
City Demarest	State NJ	ZI	P 07627	Country USA
City Demarest I hereby declare that all statements mainformation and belief are believed to be that willful false statements and the like U.S.C. 1001 and that such willful false issued thereon.	e true; and ruitie	er mat mese	fine or impris	conment, or both, under 18

NAME OF F	OURTH INVENTOR:	A petition has been filed for this unsigned inventor				
Given Name		Family Name or Surname Cost	anzo			
	whedial takes	Date: October 12, 2004				
	City Ivyland	State PA	Country USA	CitizenshipUSA		
1	dress 14 Breckenridge Drive					
City	lvyland	State PA	ZIP 18974	Country USA		

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